Remarks

Claims 11 and 23 are presented for reconsideration.

In the outstanding Office Action, the Examiner required a more descriptive title. By the above amendment, the title has been amended to better reflect the claimed invention, as helpfully suggested by the Examiner.

The Examiner also indicated that Applicant should amend the specification to delete Figures 1-8 since they provide sequence information redundant to information supplied in the sequence listings. Applicant acknowledges that 37 C.F.R. § 1.83(a) was recently amended to prohibit drawing figures duplicative of information contained in sequence listings of applications filed on or after October 21, 2004. Since the present application was filed before the new rule became effective, Applicant respectfully requests the Examiner to permit Applicant to maintain the current drawing figures to save the expense entailed in deleting such drawings and amending the corresponding specification text merely to remove redundancies.

In the Office Action, the Examiner rejected claims 11 and 23 under 35 U.S.C. § 112, second paragraph, for indefiniteness. Although Applicant believes that the scope of the previously presented claims would be understood, the claims have been amended to enhance clarity based on the Examiner's comments. In particular, the initial recitation of "an amino acid sequence" in claim 11 has been changed to "the amino acid sequence" as suggested by the Examiner. Dependent claim 23 has also been amended to replace "has" with the more typical patent parlance of "consists of" as suggested by the Examiner. In light of the amendments to the claims, the rejection for indefiniteness has been obviated.

Claims 11 and 23 were also rejected under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, as allegedly lacking utility. Applicant respectfully submits that the claimed invention is supported by a specific, substantial, and credible utility, as discussed below.

First, there is no legal precedent setting forth a *per se* rule that novel biological molecules "must undergo extensive experimentation to determine an appropriate specific,

substantial, and credible utility", as argued by the Examiner in paragraph 9 of the Office Action. Indeed, M.P.E.P. § 2107.02(III)(B) cautions against starting with a presumption that an asserted utility is *per se* incredible and then proceeding to base a Section 101 rejection on that presumption. In determining whether the utility requirement has been met, the proper presumption is that Applicant's statement of utility is correct. See, e.g., In re Langer, 503 F.2d 1380, 183 U.S.P.Q. 288 (CCPA 1965).

Thus, the initial burden is not on Applicant to prove utility, but on the USPTO to provide evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility. See, e.g., In re Brana, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995). Here, the Examiner has failed to establish a *prima facie* case of lack of utility.

Contrary to the Examiner's argument at paragraph 12 of the outstanding Office Action, the specification does identify a specific, substantial utility for the claimed invention. For example, the specification indicates that the claimed protein may be used to identify modulators of the VR3 receptor, which should have utility as therapeutic agents in treating certain medical conditions or diseases, such as pain (see specification, page 3). Accordingly, a real-world utility specific to the claimed polypeptide has been identified.

Similarly, notwithstanding the Examiner's contention to the contrary at paragraph 12 of the Office Action, the specification does identify biological functions of the claimed protein. For example, the specification provides evidence of several biological properties of hVR3 and its associated protein, including experimental results reflecting that all three isoforms of VR3 function to enhance heat-induced response (see Fig. 10 and its description; Example 5). Thus, the activities and functions are not purely conjectural or based solely on the protein being identified as a member of the TRP vanilloid (TRPV) subfamily. In fact, the Examiner apparently recognizes as much, considering that paragraph 10 of the Office Action refers to Applicant's "*showing* of increased responsiveness to heat" (emphasis added).

Applicant submits that artisans would not doubt the asserted utility in light of sequence homology of the claimed protein to known members of the TRPV subfamily

coupled with the showing of increased responsiveness to heat. The Examiner has cited no art to the contrary, which is not surprising since the literature reflects that other members of the subfamily appear to be involved in the sensation of pain-producing heat (see specification, page 2).

The art that the Examiner did cite was in reference to the argument at paragraph 14 of the Office Action that the various members of the TRPV subfamily have different properties or functions. That different members of the TRPV subfamily have different properties or functions (as noted in the specification) is of little import, however, since it follows from the fact that they are not identical. That artisans would not expect the claimed protein to function in a completely identical manner in all respects as other members of the TRPV subfamily does not establish that they would doubt that the protein would have the asserted utility, especially considering its similarities to other members of the subfamily and its responsiveness to heat.

In summary, the Examiner has failed to carry the USPTO's burden of making a *prima facie* showing that the claimed invention lacks utility. Tellingly, the previous Examiner responsible for this application did not doubt the asserted utility, for that Examiner indicated that the claimed subject matter was allowable. Applicant requests the present Examiner to likewise recognize the credibility of the asserted utility for the claimed invention, and accordingly withdraw the rejections under Section 101 and the first paragraph of Section 112.

Claim 11 was additionally rejected under 35 U.S.C. § 102(e) as supposedly being anticipated by Masters et al. (WO 01/34805). This rejection should also be withdrawn. Although the Masters et al. published PCT application claims the benefit of priority based on a US application filed November 12, 1999, the PCT application does not have an international filing date on or after November 29, 2000, and does not designate the United States. Consequently, the Masters et al. publication does not qualify as prior art under Section 102(e). See M.P.E.P. § 1857.01. Accordingly, the issue of whether any

sequence disclosed in the Masters et al. publication is encompassed by the sequence defined in claim 11 has been rendered moot.

In view of the foregoing, the application is in condition for allowance. Accordingly, prompt and favorable action is earnestly solicited.

Respectfully submitted,

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